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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/300,173	04/27/99	BYUN Y	T9005

020450
ALAN J HOWARTH
PO BOX 1909
SANDY UT 84091

HM22/0804

EXAMINER
FONDA,K

ART UNIT	PAPER NUMBER
1623	3

DATE MAILED: 08/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/300,173	Applicant(s) Byun et al.
	Examiner Kathleen Kahler Fonda	Group Art Unit 1623

☒ Responsive to communication(s) filed on *7-9-99*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5 and 7-20* is/are rejected.

☒ Claim(s) *6* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-11, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by DIANCOURT *et al*. (K). DIANCOURT teaches compounds referred to therein as CHOHEP and STEHEP, which are cholic acid and stearic acid covalently bound to heparin, respectively; see Scheme 2 and the first full paragraph on page 209. A molecular weight within the broad range of claim 4 is an inherent property of the heparin employed by DIANCOURT. With regard to claim 9, although the mole ratio of the reference cannot be calculated precisely based on the information provided, it flows inherently from the inherent molecular weight. As for claims 10, 11, and 16, DIANCOURT teaches an aqueous solution of CHOHEP in the fourth paragraph on page 216. The claims are therefore anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DIANCOURT *et al.* (K) in view of CASEY *et al.* (B).

Applicant claims a pharmaceutical composition comprising a hydrophobic agent selected from the group consisting of bile acids, sterols, and alkanoic acids covalently bound to a polysaccharide, and a carrier. Claim 13 requires that the

carrier be a sustained release polymeric matrix, and claim 15 requires that the polymeric matrix be a poly((ethylene oxide)-poly(ε-caprolactone)) copolymer. In claim 16, the polysaccharide is required to be heparin. Applicant also claims a method of inhibiting blood coagulation on a medical device by coating the device with such a pharmaceutical composition.

DIANCOURT teaches as set forth above. DIANCOURT does not teach a sustained release polymeric matrix as a carrier, or a coating for a medical device.

At column 1, lines 9-25, CASEY suggests the use of a poly((ethylene oxide)-poly(ε-caprolactone)) copolymer as a biodegradable hydrogel material for sutures or suture coatings.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to substitute a hydrogel such as a poly((ethylene oxide)-poly(ε-caprolactone)) copolymer as taught by CASEY for the carrier of DIANCOURT. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because CASEY had suggested the utility of such carriers as biodegradable hydrogel materials, and that the could be used as coatings for sutures.

Claims 10-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DIANCOURT *et al.* (K) in view of PATNAIK *et al.* (A).

Applicant claims as set forth above.

DIANCOURT teaches as set forth above. DIANCOURT does not teach a sustained release polymeric matrix as a carrier, or a coating for a medical device.

At column 9, lines 31-37, PATNAIK teaches a pharmaceutical composition comprising heparin covalently via an amide linkage to a polyurethane polymer (polyesterurethane). PATNAIK further teaches coating the composition onto a medical article at column 12, lines 22-34.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to substitute a polyurethane polymer as taught by PATNAIK, or other art-recognized biocompatible polymer, for the carrier of DIANCOURT. An ordinarily skilled worker would have been motivated to do so, with a reasonable expectation of success, because PATNAIK had suggested the pharmaceutical utility of such carriers, and that they could be used as antithrombotic coatings for medical articles.

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No prior art of record teaches or suggests heparin covalently bound to a sterol as in claim 6.

Berlowitz-Tarrant *et al.* (C) is cited to indicate the state of the art at the time of the invention more completely. The reference teaches a variety of polymers which may be used for preparation of non-thrombogenic biomedical articles.

To summarize, claim 6 is objected to, but recites allowable subject matter. Claims 1-5 and 7-20 are rejected.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Tuesday through Friday, and on

alternating Mondays, from 7:30 a.m. until 5:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner Gary Geist at (703) 308-1701. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda, Ph.D.
Primary Examiner
Art Unit 1623